115. The method of claim 112, wherein the ablation energy is one or more energies from the group consisting of: radiofrequency, microwave, and cryogenic.

Cont a1

116. The method of claim 112, wherein the means for directionally controlling the ablation energy is a shield device adapted to direct the ablation energy in a single direction along a longitudinal axis of the ablation device, whereby the step of applying ablation energy results in the creation of a continuous lesion.

117. The method of claim 116, wherein the step of applying ablation energy results in the isolation of at least one pulmonary vein from the epicardial surface of a patient's heart.--

---

REMARKS

Claims 81-117 have been added. Claims 1-117 are now pending in this case. Support for the newly added claims can be found throughout the application as originally filed.

Please charge Deposit Account No. 50-1894 $120.00 for the newly added independent claims and $333.00 for the newly added number of claims in excess of 20. Applicants request that any fee or additional fee due be charged to or any overpayment credited to Deposit Account No. 50-1894. Applicant is entitled to Small Entity Status under 37 C.F.R. §1.27.

Dated: 3-JULY-01

Ross M. Carothers

Ross M. Carothers
Patent Agent for Applicants
Reg. No. 44,593

AFx, Inc.
47929 Fremont Blvd.
Fremont, CA 94538
(510) 651-7430

Appendix of Pending Claims

All currently pending claims are reproduced below for the Examiner's convenience.

1. A flexible microwave antenna assembly for a surgical ablation instrument adapted to ablate a surface of a biological tissue, said ablation instrument including a transmission line having a proximal portion suitable for connection to an electromagnetic energy source, said antenna assembly comprising:

a flexible antenna coupled to the transmission line for radially generating an electric field sufficiently strong to cause tissue ablation;

a flexible shield device coupled to said antenna to substantially shield a surrounding area of the antenna from the electric field radially generated therefrom while permitting a majority of the field to be directed generally in a predetermined direction; and

a flexible insulator disposed between the shield device and the antenna, and defining a window portion enabling the transmission of the directed electric field in the predetermined direction,

wherein said antenna, said shield device and said insulator are formed for selective manipulative bending thereof, as a unit, to one of a plurality of contact positions to generally conform said window portion to the biological tissue surface to be ablated.

2. The microwave antenna assembly according to claim 1 wherein,

a proximal end of said antenna is operably coupled to a distal end of an inner conductor of said transmission line, and

a proximal end of said shield device is operably coupled to a distal end of an outer conductor of said transmission line.

3. The microwave antenna assembly according to claim 1 wherein,

said insulator is generally elongated when oriented in a substantially linear normal position.

4. The microwave antenna assembly according to claim 3 wherein,

said antenna is disposed between the shield device and the window portion longitudinally along said insulator.

5. The microwave antenna assembly according to claim 4 wherein,

said window portion is substantially planar in the normal position.

6. The microwave antenna assembly according to claim 4 wherein,

a longitudinal axis of said antenna is off-set from a longitudinal axis of said insulator to position said antenna substantially proximate to and adjacent said window portion.

7. The microwave antenna assembly according to claim 4 wherein,

said shield device is in the shape of a semi-cylindrical or semi-ellipsoid shell having a longitudinal axis generally co-axial with a longitudinal axis of said insulator.

8. The microwave antenna assembly according to claim 7 wherein,

a longitudinal axis of said antenna is off-set from a longitudinal axis of said insulator to position said antenna substantially proximate to and adjacent said window portion.

9. The microwave antenna assembly according to claim 2 wherein,

said shield device includes a flexible braided metallic strip.

10. The microwave antenna assembly according to claim 9 wherein,

said shield device is in the shape of a semi-cylindrical shell having a longitudinal axis generally co-axial with a longitudinal axis of said insulator.

11. The microwave antenna assembly according to claim 1 wherein,

said insulator is composed of a dielectric material adapted to minimize the energy transfer between the electromagnetic wave and the material.

12. The microwave antenna assembly according to claim 11 wherein,

said material consists essentially of TEFLON®, silicone, polyethylene, and polyimide.

13. The microwave antenna assembly according to claim 1 wherein,

said insulator defines a receiving passage formed for sliding receipt of said antenna longitudinal therein during manipulative bending of the antenna assembly.

14. The microwave antenna assembly according to claim 13 further including:

a tube device positioned in said receiving passage proximate the distal end of said antenna, and having a bore formed and dimensioned sliding longitudinal reciprocation therein of at least the distal end of said antenna.

15. The microwave antenna assembly according to claim 14 wherein,

said tube device is composed of a material having a low loss dielectric material

16. The microwave antenna assembly according to claim 15 wherein,

said tube device is a polyimide tube.

17. The microwave ablation instrument according to claim 13 further including:

an elongated, bendable, retaining member coupled longitudinally therealong to said insulator in a manner enabling the insulator to retain the one contact position after manipulative bending thereof for said conformance of the window portion to the biological tissue surface to be ablated.

18. The microwave antenna assembly according to claim 1 further including:

an elongated, bendable, retaining member coupled longitudinally therealong to said insulator in a manner enabling the insulator to retain the one contact position after manipulative bending thereof for said conformance of the window portion to the biological tissue surface to be ablated.

19. The microwave antenna assembly according to claim 18 wherein,

said retaining member is embedded in the flexible insulator.

20. The microwave antenna assembly according to claim 19 wherein,

said retaining member is composed of a metallic material having a transverse cross-sectional dimension sufficient to resist the resiliency of said insulator back to the normal position .

21. The microwave antenna assembly according to claim 17 wherein,

said retaining member is disposed longitudinally along said insulator, and on one said of said shield device, and

said antenna is disposed on an opposite side of said shield device, longitudinally along said insulator, and between the shield device and the window portion.

22. The microwave antenna assembly according to claim 21 wherein,

a longitudinal axis of said antenna is off-set from a longitudinal axis of said insulator to position said antenna substantially proximate to and adjacent said window portion.

23. The microwave antenna assembly according to claim 22 wherein,

said shield device is in the shape of a semi-cylindrical shell having a longitudinal axis generally co-axial with a longitudinal axis of said insulator.

24. A microwave ablation instrument adapted to ablate a surface of a biological tissue comprising:

a handle member formed for manual manipulation of said ablation instrument;

an elongated transmission line coupled to said handle member, and having a proximal portion suitable for connection to an electromagnetic energy source; and

a flexible antenna assembly coupled to said handle member and to the transmission line, and adapted to transmit an electric field out of a window portion thereof sufficiently strong to cause tissue ablation, said antenna assembly being formed for selective manipulative bending thereof to one of a plurality of contact positions to generally conform said window portion to the biological tissue surface to be ablated.

25. The microwave ablation instrument according to claim 24 wherein,
said antenna assembly includes:

a flexible antenna coupled to the transmission line for radially generating said electric field; and

a flexible shield device to substantially shield a surrounding radial area of the antenna from the electric field radially generated therefrom while permitting a majority of the field to be directed generally in a predetermined direction.

26. The microwave ablation instrument according to claim 24 wherein,

said antenna assembly further includes a flexible insulator disposed between the shield device and the antenna, and defining said window portion enabling the transmission of the directed electric field in the predetermined direction, said antenna, said shield device and said insulator being formed for selective manipulative bending thereof, as a unit, to said one of a plurality of contact positions.

27. The microwave ablation instrument according to claim 26 further including:
a bendable, malleable shaft having a proximal portion coupled to said handle member, and an opposite a distal portion coupled to said antenna assembly.

28. The microwave ablation instrument according to claim 27 wherein,

a proximal end of said antenna is operably coupled to a distal end of an inner conductor of said transmission line, and

a proximal end of said shield device is operably coupled to a distal end of an outer conductor of said transmission line.

29. The microwave ablation instrument according to claim 28 wherein,

said shaft is tubular and conductive having a distal portion conductively coupled to the proximal end of said shield device, and another portion conductively coupled to said outer conductor of said transmission line in a manner causing said shaft to form part of said transmission line.

30. The microwave ablation instrument according to claim 28 wherein,

said shaft is provided by a semi-rigid coaxial cable including an outer conductor and an inner conductor, the coaxial cable outer conductor having a distal portion conductively coupled to the proximal end of said shield device, and another portion of the coaxial cable outer conductor conductively coupled to said outer conductor of said transmission line, and the coaxial cable inner conductor having a proximal portion conductively coupled to a distal end of said inner conductor of said transmission line.

31. The microwave ablation instrument according to claim 28 wherein,

said insulator is coupled to the distal portion of said shaft, and generally cylindrical-shaped when oriented in a substantially linear normal position.

32. The microwave ablation instrument according to claim 31 wherein,

said antenna is disposed between the shield device and the window portion longitudinally along said insulator.

33. The microwave ablation instrument according to claim 32 wherein,

said window portion is substantially planar in the normal position.

34. The microwave ablation instrument according to claim 33 wherein,

said shield device is in the shape of a semi-cylindrical shell having a longitudinal axis generally co-axial with a longitudinal axis of said insulator.

35. The microwave ablation instrument according to claim 34 wherein,

a longitudinal axis of said antenna is off-set from a longitudinal axis of said insulator to position said antenna substantially proximate to and adjacent said window portion.

36. The microwave ablation instrument according to claim 35 wherein,

said shield device includes a flexible braided metallic strip.

37. The microwave ablation instrument according to claim 34 further including:

an elongated, bendable, retaining member coupled longitudinally therealong to said insulator in a manner enabling the insulator to retain the one contact position after manipulative bending thereof for said conformance of the window portion to the biological tissue surface to be ablated.

38. The microwave ablation instrument according to claim 28 wherein,

said insulator is comprised of a hydro-phobic material molded to the distal portion of said shaft.

39. The microwave ablation instrument according to claim 26 wherein,

said insulator defines a receiving passage formed for sliding receipt of said antenna longitudinal therein during manipulative bending of the antenna assembly.

40. The microwave ablation instrument according to claim 26 further including:

a tube device positioned in said receiving passage proximate the distal end of said antenna, and having a bore formed and dimensioned for sliding longitudinal reciprocation therein of at least the distal end of said antenna.

41. The microwave ablation instrument according to claim 40 further including:

an elongated, bendable, retaining member coupled longitudinally therealong to said insulator in a manner enabling the insulator to retain the one contact position after manipulative bending thereof for said conformance of the window portion to the biological tissue surface to be ablated.

42. The microwave ablation instrument according to claim 26 further including:

an elongated, bendable, retaining member coupled longitudinally therealong to said insulator in a manner enabling the insulator to retain the one contact position after manipulative bending thereof for said conformance of the window portion to the biological tissue surface to be ablated.

43. The microwave ablation instrument according to claim 42 wherein,

said retaining member is embedded in the flexible insulator.

44. The microwave ablation instrument according to claim 42 wherein,

said retaining member is composed of a metallic material having a transverse cross-sectional dimension sufficient to resist the resiliency of said insulator back to the normal position.

45. The microwave ablation instrument according to claim 44 wherein,

said retaining member is disposed longitudinally along said insulator, and on one said of said shield device, and

said antenna is disposed on an opposite side of said shield device, longitudinally along said insulator, and between the shield device and the window portion.

46. The microwave ablation instrument according to claim 30 further including:

a restraining sleeve adapted to limit the bending movement of said bendable antenna assembly at the conductive coupling between the shield device and the shaft.

47. The microwave ablation instrument according to claim 46 wherein,

said restraining sleeve is formed and dimensioned to extend peripherally over the conductive coupling to limit said bending movement in a predetermined direction to maintain the integrity of conductive coupling.

48. The microwave ablation instrument according to claim 47 wherein,

said shield device is in the shape of a semi-cylindrical shell having a longitudinal axis generally co-axial with a longitudinal axis of said insulator, and

said restraining sleeve includes a curvilinear transverse cross-sectional dimension extending past said conductive coupling longitudinally therealong by an amount sufficient to maintain said integrity.

49. The microwave ablation instrument according to claim 29 wherein:

the transmission line is a coaxial transmission line suitable for transmission of microwave energy at frequencies in the range of approximately 800 to 6000 megahertz, the coaxial transmission line having a center conductor, a shield and a dielectric material disposed between the center conductor and shield.

50. The microwave ablation instrument according to claim 26 further including:

an elongated gripping member having a distal grip portion and an opposite proximal portion coupled to a distal portion of said antenna assembly, said grip member and said handle member cooperating to selectively bend said antenna assembly and selectively urge the window portion in abutting contact with the biological tissue surface to be ablated.

51. The microwave ablation instrument according to claim 50 wherein,

said insulator defines a receiving passage formed for sliding receipt of said antenna longitudinal therein during manipulative bending of the antenna assembly.

52. The microwave ablation instrument according to claim 50 wherein,

said gripping member is provided by an elongated flexible rod having a diameter smaller than a diameter of said insulator.

53. The microwave ablation instrument according to claim 52 wherein,

a longitudinal axis of said antenna is off-set from a longitudinal axis of said insulator to position said antenna substantially proximate to and adjacent said window portion, and
a longitudinal axis of said flexible rod is off-set from the longitudinal axis of said insulator to position said rod in general axial alignment with said antenna, and adjacent said window portion.

54. The microwave ablation instrument according to claim 50, wherein

said handle member is a flexible elongated member having a proximal portion coupled to said transmission line, and an opposite a distal portion coupled to said antenna assembly.

55. The microwave ablation instrument according to claim 54, wherein

said flexible elongated member is a coaxial cable including an outer conductor and an inner conductor, the coaxial cable outer conductor having a distal portion conductively coupled to the proximal end of said shield device, and another portion of the coaxial cable outer conductor conductively coupled to said outer conductor of said transmission line, and the coaxial cable inner conductor having a proximal portion conductively coupled to a distal end of said inner conductor of said transmission line.

56. A method for treatment of a heart comprising:

providing an ablation instrument having a flexible antenna assembly defining a window portion enabling the transmission of a directed electric field therethrough in a predetermined direction;

selectively bending the flexible antenna assembly to one of a plurality of contact positions to generally conform the shape of said window portion to the targeted biological tissue surface to be ablated;

manipulating the ablation instrument to strategically position the conformed window portion into contact with the targeted biological tissue surface; and

generating the electric field sufficiently strong to cause tissue ablation to the targeted biological tissue surface.

57. The method of claim 56, wherein

said flexible antenna assembly includes:

a flexible antenna for radially generating the electric field;

a flexible shield device coupled to said antenna to substantially shield a surrounding area of the antenna from the electric field radially generated therefrom while permitting a majority of the field to be directed generally in the predetermined direction; and

a flexible insulator disposed between the shield device and the antenna, and defining said window portion enabling the transmission of the directed electric field in the predetermined direction.

58. The method of claim 57, further including:

repeating the bending, manipulating and generating events to form a plurality of strategically positioned ablation lesions.

59. The method of claim 58, wherein

the lesions are formed to create a predetermined conduction pathway in the muscular tissue wall of the targeted biological tissue and/or to divide the left and/or right atria to substantially prevent reentry circuits.

60. The method of claim 57, further including:

an elongated, bendable, retaining member coupled longitudinally therealong to said insulator in a manner enabling the insulator to retain the one contact position after manipulative bending thereof for said conformance of the window portion to the biological tissue surface to be ablated.

61. The method of claim 60, wherein

said retaining member is embedded in the flexible insulator.

62. The method of claim 56, wherein

the heart remains beating throughout the bending, manipulating and generating events.

63. The method of claim 56, further including:

arresting the patient's heart.

64. The method of claim 56, further including:

temporarily arresting the patient's heart.

65. The method of claim 56, wherein

said ablation instrument is a microwave ablation instrument.

66. A method for ablating medically refractory atrial fibrillation of the heart comprising:

providing an ablation instrument having a flexible antenna assembly adapted to generate an electric field sufficiently strong to cause tissue ablation, said antenna assembly defining a window portion enabling the transmission of the electric field therethrough in a predetermined direction;

selectively bending and retaining the flexible antenna assembly in one of a plurality of contact positions to generally conform the shape of said window portion to the targeted biological tissue surface to be ablated;

manipulating the ablation instrument to strategically position the conformed window portion into contact with the targeted biological tissue surface; and

forming an elongated lesion in the targeted biological tissue surface through the generation of the electric field by the antenna assembly.

67. The method of claim 66, wherein

said flexible antenna assembly includes:

a flexible antenna for radially generating the electric field;

a flexible shield device coupled to said antenna to substantially shield a surrounding area of the antenna from the electric field radially generated therefrom while permitting a majority of the field to be directed generally in the predetermined direction; and

a flexible insulator disposed between the shield device and the antenna, and defining said window portion enabling the transmission of the directed electric field in the predetermined direction.

68. The method of claim 67, further including:

repeating the bending, manipulating and generating events to form a plurality of strategically positioned ablation lesions and/or to divide the left and/or right atria to substantially prevent reentry circuits.

69. The method of claim 68, wherein

the lesions are formed to create a predetermined conduction pathway between a sinoatrial node and an atrioventricular node of the heart.

70. The method of claim 68, wherein

said repeating the bending, manipulating and generating events are applied in a manner isolating the pulmonary veins from the epicardium of the heart.

71. The method of claim 67, further including:

an elongated, bendable, retaining member coupled longitudinally therealong to said insulator in a manner enabling the insulator to retain the one contact position after manipulative bending thereof for said conformance of the window portion to the biological tissue surface to be ablated.

72. The method of claim 71, wherein

said retaining member is embedded in the flexible insulator.

73. The method of claim 66, wherein

the heart remains beating throughout the bending, manipulating and generating events.

74. The method of claim 73, wherein

said biological tissue surface includes the epicardium of the heart during a minimally invasive heart procedure.

75. The method of claim 66, further including:

arresting the patient's heart.

76. The method of claim 66, further including:

temporarily arresting the patient's heart.

77. The method of claim 75, wherein

said biological tissue surface includes the endocardium of one of the left atrium and the right atrium during an open-heart procedure.

78. The method of claim 65, wherein

said ablation instrument is a microwave ablation instrument.

79. The method of claim 66, wherein

said ablation instrument includes an elongated flexible gripping member having a distal grip portion and an opposite proximal portion coupled to a distal portion of said antenna assembly, and a handle member coupled to a proximal portion of said antenna assembly; and

said manipulating includes manually gripping said flexible gripping member and said handle member to cooperatively and selectively bend said antenna assembly to selectively urge the window portion in abutting contact with the biological tissue surface to be ablated.

80. The method of claim 79, wherein

said handle member is a flexible elongated member.

81. An energy delivery device for ablating biological tissue, comprising:

a flexible ablation assembly, comprising:

a flexible ablation device; and

a means for directionally controlling ablation energy emitted therefrom.

82. The device of claim 81, wherein the flexible ablation device comprises at least one ablation element for emitting ablation energy sufficient to ablate biological tissue.

83. The device of claim 82, wherein the flexible ablation assembly defines an outer ablation surface from which ablation energy is emitted.

84. The device of claim 83, wherein the at least one ablation element is flexible.

85. The device of claim 84, wherein the at least one flexible ablation element is disposed within the ablation assembly.

86. The device of claim 83, wherein the ablation assembly further comprises an insulating element, the insulating element holding the ablation element in a fixed position relative to the ablating surface.

87. The device of claim 86, wherein an exterior surface of the insulating element defines the outer ablation surface.

88. The device of claim 87, wherein the insulating element is adapted to be substantially transparent to the ablation energy emitted therethrough by the at least one flexible ablation element.

89. The device of claim 88, wherein the means for directionally controlling the ablation energy is flexible.

90. The device of claim 87, wherein the means for directionally controlling the ablation energy is a shield device, whereby a portion of biological tissue adjacent to the ablation surface is shielded from the ablation energy.

91. The device of claim 90, wherein the shield device is adapted to at least partially reflect ablation energy emitted by the at least one ablation element.

92. The device of claim 91, wherein the shield device is flexible.

93. The device of claim 92, wherein the at least one ablation element is an antenna adapted to emit electromagnetic energy.

94. The device of claim 93, wherein the at least one ablation element is adapted to emit electromagnetic energy in the microwave range.

95. The device of claim 94, wherein the electromagnetic energy is at about 434MHz.

96. The device of claim 94, wherein the electromagnetic energy is at about 915MHz.

97. The device of claim 94, wherein the electromagnetic energy is at about 2.45 GHz.

98. The device of claim 94, wherein the electromagnetic energy is at about 5.8 GHz.

99. The device of claim 94, wherein the antenna is a helical coil antenna.

100. The device of claim 94, wherein the antenna is a linear antenna.

101. The device of claim 90, wherein a longitudinal axis of the insulating element is generally coaxial with a longitudinal axis of the shield device.

102. The device of claim 81 further comprising a means for manual manipulation of the flexible ablation assembly.

103. The device of claim 102, wherein the manipulating means is a handle having proximal and distal ends, the flexible ablation assembly being operably attached to the distal end of the handle.

104. The device of claim 102, wherein the manipulating means is an elongated tubular member.

105. The device of claim 103 further comprising a shaft member operably disposed between the flexible ablation assembly and the handle.

106. The device of claim 105, wherein the shaft member is rigid.

107. The device of claim 106, wherein the shaft member is a metallic tube.

108. The device of claim 104, wherein the shaft member is malleable.

109. The device of claim 108, wherein the shaft member is a metallic tube.

110. The device of claim 108, wherein the shaft member is a coaxial cable.

111. An energy delivery device for ablating biological tissue, comprising:

a flexible ablation assembly defining an outer ablation surface from which ablation energy sufficient to ablate biological tissue is emitted,

wherein the ablation assembly is adapted to be manipulated to one of a plurality of contact positions to generally conform the ablation surface to the biological tissue during tissue ablation.

112. A method of ablating tissue at a target tissue site, comprising the steps:

providing a flexible ablation device defining an outer ablation surface and comprising a means for directionally controlling ablation energy emitted therefrom;

manipulating the distal portion of the ablation device to generally conform the ablation surface to a tissue surface at the target tissue site;

applying ablation energy sufficient to ablate tissue at the target tissue site.

113. The method of claim 112, wherein the ablation device comprises at least one ablation element.

114. The method of claim 113, wherein the at least one ablation element is an antenna.

115. The method of claim 112, wherein the ablation energy is one or more energies from the group consisting of: radiofrequency, microwave, and cryogenic.

116. The method of claim 112, wherein the means for directionally controlling the ablation energy is a shield device adapted to direct the ablation energy in a single direction along a longitudinal axis of the ablation device, whereby the step of applying ablation energy results in the creation of a continuous lesion.

117. The method of claim 116, wherein the step of applying ablation energy results in the isolation of at least one pulmonary vein from the epicardial surface of a patient's heart.